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10/725,483	12/03/2003	Yoshihito Fukui	034071-002	3993

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EXAMINER	
REIDEL, JESSICA L	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/725,483	FUKUI, YOSHIHITO	
	Examiner	Art Unit	
	Jessica L. Reidel	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. Figures 4A, 4B, 17A, 17B, and 18 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: priority benefits must be stated in the first sentence of the specification following the title, or in an application data sheet (see MPEP 201.11). Appropriate correction is required.

3. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously

incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f). The Examiner suggests changing the disclosure to incorporate the equivalent U.S. Patents disclosed by the Applicant on the Information Disclosure Statement submitted December 9, 2004.

4. The disclosure is objected to because of the following informalities: typographical errors on page 10. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. The Examiner prosecutes the Application such that "a blood" is synonymous with "a blood sensor".

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz (U.S. 5,330,507). Schwartz discloses heart treatment equipment comprising a nerve stimulator 126 for generating a nerve stimulating signal for stimulate a vagus nerve (see Schwartz Fig. 3 and column 5, lines 20-23) via electrical leads 68 and 78 (see Schwartz column 5, lines 51-54). Schwartz further discloses heart treatment equipment comprising sensors 64, 65, 67, 69, 60', and 60" for sensing living body information of the patient (see Schwartz column 6, lines 20-26) and a controller 108, connected to the nerve stimulator and sensors, that controls the nerve stimulator in response to an output of the sensors (see Schwartz Figs. 2 and 3 and column 7, lines 25-30).

10. In addition to the arguments presented for the rejection of Claim 1, Claim 2 and Claim 3 are rejected. Schwartz also discloses a controller 108 that includes memory 110 for storing a plurality of stimulation parameters of the nerve stimulating signal and selecting at least one of the parameters from the memory in response to an output of the sensor (see Schwartz Fig. 2 column 12, lines 1-2 and column 6, lines 3-9, lines 19-26, and lines 44-49). Schwartz also discloses that the variable parameter (via logic 104 and controller 108) is a period between pulses, a pulse width, a number of pulses, a pulse current, a pulse voltage, a delay time, a rest time and a repetitive number or is a multiple combination chosen from these (see Schwartz column 6, lines 50-63).

11. In addition to the arguments presented for the rejection of Claim 1, Claim 4 is rejected. Schwartz also discloses sensors 64 and 65, located in the right ventricle, that detect ventricle contractility via the R-wave from the sensed ventricular ECG (see Schwartz Fig. 1 column 6, lines 21-22, and column 12, lines 1-2).

12. In addition to the arguments presented for the rejection of Claim 1, Claim 7 is rejected. Schwartz also discloses activity sensor 60" (see Schwartz column 6, line 26) that senses an activity.

13. In addition to the arguments presented for the rejection of Claim 1, Claim 10 is rejected. Swartz also discloses cardiac pulse generators 116 that receive stimulating pulse generation commands (see Swartz column 6, lines 63-65) responsive to increases in the heart rate greater than a predetermined threshold, the occurrence of frequent or complex ventricular arrhythmias, and/or a change in the ST segment elevation greater than a predetermined or programmed threshold (see Swartz Abstract, Fig. 2 and column 7, lines 13-19).

14. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz (U.S. 5,330,507). Schwartz discloses heart treatment equipment comprising a nerve stimulator 126 for generating a nerve stimulating signal for stimulate a vagus nerve (see Schwartz Fig. 3 and column 5, lines 20-23) via electrical leads 68 and 78 (see Schwartz column 5, lines 51-54). Schwartz further discloses heart treatment equipment comprising sensors 64, 65, 67, 69, 60', and 60" for sensing living body information of the patient input to a heart abnormal detector 100 for detecting an abnormal condition of the heart (see Schwartz column 6, lines 20-26) and a controller 108, connected to the nerve stimulator and sensors, that controls the nerve stimulator in response to an output of the sensors (see Schwartz Figs. 2 and 3 and column 7, lines 25-30).

15. In addition to the arguments presented for the rejection of Claim 11, Claim 12 and Claim 14 are rejected. Schwartz also discloses a controller 108 that includes memory 110 for storing a plurality of stimulation parameters of the nerve stimulating signal and selecting at least one of the parameters from the memory in response to an output of the heart abnormal detector 100 (see

Schwartz Fig. 2 column 12, lines 1-2 and column 6, lines 3-9, lines 19-26, and lines 44-49). Schwartz also discloses that the variable parameter (via logic 104 and controller 108) is a period between pulses, a pulse width, a number of pulses, a pulse current, a pulse voltage, a delay time, a rest time and a repetitive number or is a multiple combination chosen from these (see Schwartz column 6, lines 50-63).

16. In addition to the arguments presented for the rejection of Claim 11, Claim 13 is rejected. Schwartz also disclose a heart event detector 104 for detecting a heart event where heart abnormal detector 100 is a risk event detector connected to the heart risk event detector 104 for detecting a tachycardia risk event (see Schwartz Fig. 2 column 12, lines 1-2 and column 6, lines 3-9, lines 19-26, and lines 44-49).

17. In addition to the arguments presented for the rejections of Claim 11 and Claim 13, Claim 15 is rejected. Schwartz also discloses heart treatment equipment where the detected risk event includes an increase of a heart rate (see Schwartz Abstract line 6).

18. In addition to the arguments presented for the rejections of Claim 11 and Claim 13, Claim 16 is rejected. Schwartz also discloses heart treatment equipment where the detected risk event includes a premature contraction (see Schwartz column 4, line 55).

19. In addition to the arguments presented for the rejections of Claim 11 and Claim 13, Claim 17 and Claim 18 are rejected. Schwartz also discloses heart treatment equipment where the detected risk event includes an early after-depolarization or a delayed after-depolarization (see Schwartz column 4, lines 53-56 and column 6, lines 20-26).

20. In addition to the arguments presented for the rejections of Claim 11 and Claim 13, Claim 19 is rejected. Swartz also discloses cardiac pulse generators 116 that receive stimulating pulse

generation commands (see Swartz column 6, lines 63-65) responsive to increases in the heart rate greater than a predetermined threshold, the occurrence of frequent or complex ventricular arrhythmias, and/or a change in the ST segment elevation greater than a predetermined or programmed threshold (see Swartz Abstract, Fig. 2 and column 7, lines 13-19).

21. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz (U.S. 5,330,507). Schwartz discloses heart treatment method comprising a process for stimulating a vagus nerve via nerve stimulator 126 and (see Schwartz Fig. 3 and column 5, lines 20-23) electrical leads 68 and 78 (see Schwartz column 5, lines 51-54). Schwartz further discloses heart treatment method comprising a process for sensing living body information via sensors 64, 65, 67, 69, 60', and 60" (see Schwartz column 6, lines 20-26) and a controller 108, connected to the nerve stimulator and sensors, that controls the nerve stimulator in response to an output of the sensors (see Schwartz Figs. 2 and 3 and column 7, lines 25-30).

22. In addition to the arguments presented for the rejection of Claim 20, Claim 21 is rejected. Schwartz also discloses that the method senses living body information of a heart (see Schwartz column 6, lines 20-25).

23. Claim 22 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schwartz. In addition to the arguments presented for the rejection of Claim 20, Schwartz also discloses that the method senses living body information via a sensed signal relied upon an autonomic nerve activity since it is inherent, or at least obvious to one having ordinary skill in the art, that heart rate is determined primarily by autonomic influence of the SA node see Schwartz Abstract line 6).

24. In addition to the arguments presented for the rejection of Claim 20, Claim 23 is rejected. Schwartz also discloses that the variable parameter (via logic 104 and controller 108) is a period between pulses, a pulse width, a number of pulses, a pulse current, a pulse voltage, a delay time, a rest time and a repetitive number or is a multiple combination chosen from these (see Schwartz column 6, lines 50-63).

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

26. In addition to the arguments presented for the rejections of Claim 1 and Claim 4, Claim 5 and Claim 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz in view of Falkenberg et al. (EP 1 142 608). Schwartz discloses sensors 64 and 65, located in the right ventricle, that detect ventricle contractility via the R-wave from an intracardic electrogram area that is related to a QT interval (see Schwartz column 6, lines 21-22 and column 12, lines 30-32). Schwartz differs from Claim 5 and 6 in that the ventricle contractility is not related to one of a pre-ejection period, a stroke volume, and ventricle pressure and the controller does not control the nerve stimulator to stop the generation of the nerve stimulation signal when the ventricle contractility is out of predetermined range.

27. Falkenberg, however, teaches cardiac pacing techniques comprising controller 60 that controls various modes of stimulation therapy via commanding control signals to trigger or

inhibit stimulation pulses when the contractility is out of predetermined range (see Falkenberg Fig. 3 and column 6, lines 30-31 and lines 50-55). Falkenberg also discloses controller 60 determining contractility based on pressure, acceleration or pressure signals received from sensors, or stroke volume (see Falkenberg column 9, lines 56-58). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart treatment equipment of Schwartz in view of Falkenberg to include detecting ventricle contractility related to one of a pre-ejection period, a stroke volume, and ventricle pressure in order to increase the device's ability to determine if administering therapy is necessary, and to program the controller to control the nerve stimulator to stop the generation of the nerve stimulation signal when the ventricle contractility is out of predetermined range to improve the invention.

28. In addition to the arguments, presented for the rejection of Claim 1, Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz in view of Scheiner et al. (U.S. 6,415,183) (herein Scheiner). Schwartz differs from Claim 8 in that the sensor does not sense a respiration.

Scheiner, however, discloses an implantable electrical stimulator 100 for prevention or interruption of life threatening arrhythmias that comprises an implanted lead that senses respiration activity in order to deliver an appropriate therapeutic output based on that input. Scheiner teaches that an objective of this type of stimulator is to treat patients that not only suffer from breathing disorders but those that suffer from heart conditions that require pacing therapy and to treat both types simultaneously (see Scheiner column 1, lines 44-46). It is also well known in the art that arrhythmias cause a decrease in cardiac output and a simultaneous decrease

in respiratory activity. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart treatment equipment of Schwartz in view of Scheiner to include a sensor that senses a respiration in order to improve the device's ability to prevent fatal arrhythmia.

29. In addition to the arguments, presented for the rejection of Claim 1, Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz in view of Obel et al. (U.S. 5,199,428) (herein Obel). Schwartz differs from Claim 8 in that the sensor does not sense a blood parameter.

Obel, however, discloses a method and apparatus for maintaining adequate cardiac rate through stimulation of the vagal nervous system (or other effective nerves) as well as the heart tissue in a concentrated fashion by comparison of the patient's coronary sinus blood pH and/or oxygen saturation and/or electrocardiogram elevation to preset, normal thresholds and triggering nerve stimulation until the blood gas and/or ST segment variations have been returned to non-clinical risk levels (See Obel column 3, lines 15-28). Obel further discloses lead 66 that carries a blood sensor (see Obel coumn 5, line 66) placed in the right ventricle in order to accomplish the objective of the apparatus. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart treatment equipment of Schwartz in view of Scheiner to include a sensor that senses blood pH and/or oxygen saturation to improve the device's ability to prevent fatal arrhythmia by maintaining cardiac rate.

Conclusion

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kieval et al. (U.S. 6,073,048) (herein Kieval) discloses a system and method for stimulating a nerve in order to increase parasympathetic activity that includes a pacemaker for bradycardia support pacing.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jessica L. Reidel